U.S.S.N. 10/053,929

Filed: January 22, 2002

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In The Claims

Claims 1-15. (Canceled)

16. (Original) A method for making a pharmaceutical composition comprising a porous

matrix formed of at least one hydrophilic or hydrophobic excipient and microparticles of a drug,

wherein the microparticles have a mean diameter between about 0.1 and 5 µm and a total surface

area greater than about 0.5 m²/mL, and wherein the dry porous matrix is in a dry powder form

having a TAP density less than or equal to 1.0 g/mL and having a total surface area of greater

than or equal to 0.2 m²/g, comprising

(a) dissolving a drug in a volatile solvent to form a drug solution,

(b) combining at least one volatile solid pore forming agent with the drug solution to

form an emulsion, suspension, or second solution,

(c) incorporating at least one excipient into the emulsion, suspension, or second solution.

wherein the excipient is selected from the group consisting of hydrophobic and hydrophilic

excipients which enhance dissolution rate, which stabilize drug in amorphous form by preventing

crystallization, and which stabilize drug in crystalline form by inhibiting crystal growth, and

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(d) removing the volatile solvent and pore forming agent from the emulsion, suspension,

or second solution to yield the porous matrix of drug and excipient.

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17. (Original) The method of claim 16 wherein step (d) is conducted using a process

selected from spray drying, evaporation, fluid bed drying, lyophilization, vacuum drying, or a

combination thereof.

18. (Original) The method of claim 16 wherein the excipients are selected from the

group consisting of polymers, amino acids, wetting agents, sugars, preservatives, pegylated

excipients, tonicity agents, and combinations thereof.

19. (Original) The method of claim 16 wherein the matrix comprises between 1 and

95% drug by weight in combination with at least one hydrophilic or hydrophobic excipient

which enhances the rate of drug dissolution, stabilizes the drug in crystalline form by inhibiting

crystal growth or stabilizes the drug in amorphous form by preventing crystallization.

20. (Original) The method of claim 16 wherein the pore forming agent is a volatile salt.

21. (Original) The method of claim 20 wherein the volatile salt is selected from the

group consisting of ammonium bicarbonate, ammonium acetate, ammonium chloride,

ammonium benzoate, and mixtures thereof.

Claims 22-33. (Canceled)

34. (New) The method of claim 16, wherein the drug is selected from the group

consisting of analgesics or antipyretics, antiasthmatics, anti-inflammatories, antimigraine agents.

antiarthritic agents, anticonvulsants, antibacterial agents, antiviral agents, and antimicrobials.

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